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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,593	03/30/2004	Bernard Andreas	021629-002500US	5895

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EXAMINER	
HOUSTON, ELIZABETH	

ART UNIT	PAPER NUMBER
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/814,593	ANDREAS ET AL.	
	Examiner	Art Unit	
	ELIZABETH HOUSTON	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22 and 37-42* is/are pending in the application.

4a) Of the above claim(s) *2* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-22 and 37-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/12/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 10/637,713, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. While the prior filed application provides support for a multiple stent delivery device, it does not provide support for a method that includes delivering a stent to a first branch and delivering a second stent to a second branch where the first and second meet at a bifurcation. Applicant claims support is found is found at paragraphs [0100] and [0104] in the '713 application. Here the '713 application discloses a stent having a slot (as in fig 5B) that can be expanded by a catheter if the stent is deployed at a location in which it covers an

ostium to a side branch. While it states that a balloon dilation catheter may perform the operation of expansion, it does not states that it would be the same balloon that expanded the stent in the main branch or that it would be the same balloon that would position the additional stents in the side branch. The claims require that the expandable member expand a first stent in the main branch and the expandable member expands the second stent in the side branch, where the main branch and the side branch meet at a bifurcation. Thus the claimed invention does not find support in the previously filed application 10/637,713. Therefore the effective filing date for the purposes of applying prior art will be the filing date of the instant application, 03/30/2004.

Claim Objections

2. Claim 12 is objected to because of the following informalities: To avoid a negative recitation, the limitation “is not removed from” should be more clearly stated by terminology such as “remains in”. Appropriate correction is required.

3. Claim 12 is objected to because of the following informalities: The limitation “between deploying the first and second stents” lacks antecedent basis in the claim due to the amendment removing the previously recited step of “deploying”. Examiner suggests changing the limitation to “expanding” to maintain consistency. Appropriate correction is required.

4. Claims 19 and 20 objected to because of the following informalities: It is unclear whether the limitation “expanding an expandable member” finds antecedent basis in the “expanding” limitation in claim 12. Examiner suggests inserting "*the step of* expanding

the expandable member" in order to clearly refer back to the previously recited step and to maintain consistency. Appropriate correction is required.

5. Claims 38 and 39 are objected to because of the following informalities: It is unclear whether the limitation “selecting” finds antecedent basis in the “selecting” limitation in claim 37. Examiner suggests inserting "*the step of* selecting” in order to clearly refer back to the previously recited step and to maintain consistency. Appropriate correction is required.

6. Claims 41 and 42 are objected to because of the following informalities: It is unclear whether the limitation “selecting” finds antecedent basis in the “selecting” limitation in claim 40. Examiner suggests inserting "*the step of* selecting” in order to clearly refer back to the previously recited step and to maintain consistency. Appropriate correction is required.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1, 3-10, 12, 13, 17-21, 37-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (US 2002/0156496) in view of Brucker (US 2002/0793873).

9. Chermoni discloses a method of treating one or more lesions in a vessel comprising:

a. Positioning a delivery catheter (Fig. 11) in a main branch having an expandable member (704) thereon and radially expanding the expandable member thereby radially expanding a first stent (206a) in the main branch (Para 009).

b. positioning the delivery catheter at a different location and radially expanding the expandable member thereby radially expanding a second stent (206b) wherein the delivery catheter is not removed from the vessel between deploying the first and second stents (Para [0009[).

c. The first and second stents each comprise a plurality of separable segments (where the segments are struts which are separable upon expansion of the stent).

d. the first stent has a different length than the second stent (Para [0005]; [0047])

e. The first stent can be deployed before the second stent or the second stent can be deployed before the first stent (Para [0049]).

f. Adjusting the length of the first stent and adjusting the length of the second stent before deploying while the catheter remains in the body (Para [0008] states that the stents may be delivered in any order and may be different lengths and so the lengths are adjusted by choosing a different order of stents).

g. Selecting the first number of separable segments for radial expansion, the first number of segments having a first length and selecting a second number of the separable segments for radial expansion, the second number of segments having a second length. (Para [0008] states that the stents may be delivered in any order and may be different lengths. Each length will have a different number of separable segments (struts). Therefore the number of separable segments is selected by choosing the order of the different lengthed stents to be delivered.)

h. Selecting either the first number or the second number comprises moving a sheath or a pusher tube (114 can be either the sheath or the pusher tube) (Para 0048).

10. Chermoni does not disclose where the method of treating more than one lesion is in a vessel that has a main branch and a side branch branching from a main branch or that the delivery catheter is positioned through an opening in a sidewall of the first stent to deploy the second stent.

11. However, Brucker discloses a method of treating one or more lesions in a vessel, the vessel having a main branch and a side branch branching from the main branch at a bifurcation, the method comprising similar steps to those that are disclosed by Chermoni such as positioning the delivery catheter at multiple lesions and expanding first and second stents at different locations without removing the catheter from the body. Brucker further discloses

i. positioning a delivery catheter (112) in the main branch, and radially expanding the expandable member thereby radially expanding a first stent (94 or 114) in the main branch (Fig. 13, 14, 17 and 18; Para [0083])

j. positioning the delivery catheter in the side branch and radially expanding an expandable member (120) thereby radially expanding a second stent (74 or 116) in the side branch (Fig. 10-12, 20, Para [0084]); wherein the delivery catheter is not removed from the vessel between deploying the first and second stents (see Figs. 18-20; Para [0084]).

k. the delivery catheter is positioned through an opening (16) in a sidewall of the first stent to deploy the second stent (Fig. 20).

l. Wherein the first stent and the second stent each have a portion in the main branch. (Fig. 14, 16, 17).

m. further comprising dilating the opening in the sidewall of the first stent by expanding an expandable member on the delivery catheter (Para [0084] states that the first stent has a scaffold for engaging the second stent thus indicating that the opening in the sidewall of the first stent would be dilated at the very least when the second stent is dilated in the same overlapping location.)

n. the first stent has a different geometry than the second stent (the first stent has a sidewall opening).

o. deploying the first stent comprises expanding an expandable member (118) on the delivery catheter and deploying the second stent comprises expanding an expandable member (120) on the delivery catheter

p. At least one of the first and second stents comprises a plurality of separable segments (where each strut is a segment and separable when the stent is expanded).

It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the method of treating a bifurcated vessel into the method and apparatus of Chermoni. Both Chermoni and Brucker disclose similar devices for multiple stent delivery. Brucker discloses an additional method of delivering the multiple stents to lesions in a bifurcated vessel having a main vessel and a branch vessel. One of ordinary skill would have been capable of applying this known technique of enhancement (delivering stents to a bifurcated vessel) to a base device (multiple stent delivery catheter) in order to yield predictable results. If a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, applying the technique to a similar device would have been obvious.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (US 2002/0156496) in view of Brucker et al. (US 2002/0193873) as applied to claim 12 above and further in view of Loos et al (US 6,579,309).

14. Chermoni modified by Brucker discloses a method of treating a lesion in a bifurcation but does not disclose that the stent delivered to the main branch has an opening that is I-shaped or that the stent has first slots that are larger than second slots.

15. Loos discloses a stent that is intended to be delivered to a main branch of a bifurcation. The stent has side openings that are I-shaped (Fig. 3, for example where Arrows 19 and 20 are pointing). The stent has a plurality of first slots (I shaped openings) larger than a plurality of second slots (for example where 13 and 18) are pointing. The first slots are intended to be aligned with the bifurcation.

16. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the stent of Loos into the delivery device and method of Chermoni modified by Brucker. Chermoni modified by Brucker discloses the claimed method except for a stent with a flower shaped opening rather than an I-shaped opening. Loos shows that a stent with an I-shaped opening is an equivalent structure known in the art. Therefore, because the two stents were art recognized equivalents at the time of the invention was made, one of ordinary skill in the art would have found it obvious to substitute the I-shaped opening for the flower shaped opening, since substitution of one known element for another would have yielded predictable results.

17. Claims 11and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni in view of Brucker as applied to claims 1 and 12 above and further in view of Shaknovich (US 5,807,398).

18. Chermoni modified by Brucker does not explicitly state the step of dilating at least one lesion in the vessel using an expandable member on the delivery catheter before deploying at least one of the first and second stents. However, Chermoni does contemplate the multiple steps of balloon angioplasty and stent delivery when discussing prior art (Para [003]).

19. Shaknovich discloses a single catheter multiple stent delivery device similar to Chermoni modified by Brucker and explicitly discloses using the expandable member to pre-dilate a vessel prior to stent delivery in order to provide an adequate passageway for the delivery catheter (C 12: 20-29).

20. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the step of dilating a lesion prior to stent delivery into the method disclosed by Chermoni modified by Brucker. Pre-dilating the vessel prior to stent delivery is old and well known in the art and provides the advantage of increasing the diameter of the passage to allow the catheter to get through.

Response to Arguments

21. Applicant's arguments filed 02/28/08 have been fully considered but they are not persuasive. Regarding the Loos reference applicant states that the Loos stent would not be able to properly be deployed with out a dual balloon catheter having a guidewire port

in the middle as disclosed by Loos. However, Loos discloses that this is merely a preferred method of delivery (C 6: L56-58) and that the stent can be delivered with other balloon configurations (C7: L18-22). Additionally, Loos discloses that the elements are pivoted into the side branch by means of guidewire (C 7: L11-17) but does not require specifically that the guidewire come from in between two balloons.

22. Applicant's arguments with respect to claims 1, 3-13 and 17-22 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./
Examiner, Art Unit 3731
/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731